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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,196	03/23/2000	ROGER JOHN DALY	187I-129	8868

24353 7590 10/26/2004
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,196	DALY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-7,19-22,24-29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5-7,19-22,24-29,31 and 32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>10/18/04</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30, 2004 has been entered.

2. Claim 32 has been added as requested in the amendment filed on August 30, 2004. Claims 1, 5-7, 19-22, 24-29 and 31-32 are pending in the instant application.

Claims 1, 5-7, 19-22, 24-29 and 31-32 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on August 30, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claims 1, 5-7, 19-22, 24-29 and 31-32 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in appropriate sections of Papers mailed on 04/02/2001, 12/03/2001; 11/05/2002; 8/19/2003 and 01/30/2004 No. 12. Briefly, the instant application has

provided a description of an isolated DNA encoding a protein and the protein encoded thereby.

The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Beginning at the middle of page 6 of the Response, Applicant presents citations from The Utility Examination Guidelines, appropriate section of MPEP and summarizes case law on the utility requirement. Applicant submits that the asserted utility of the claimed polynucleotides encoding 2.2412 protein as tumor markers is fully supported by the instant specification, as originally filed, as well as additional data provided in Hitoshi Declaration (page 7-12 of the Response). These arguments have been carefully considered and fully answered before in the previous office actions of record. Briefly, the assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, wherein Grb proteins maybe associated with cancer, does not provide a scientific basis to conclude that the instant DNA or encoded protein can be used as tumor markers. There appears to be no information presented in the instant specification, as filed, such as, for example, data showing differential expression of 2.2412 protein in healthy *versus* cancerous tissue, or a mutated form of a polynucleotide specifically associated with certain types of cancer, that would allow one skilled in the art to conclude that the claimed 2.2412 polynucleotides could be used to diagnose cancer. With regards to Declaration of Hitoshi, as it was fully explained earlier in the previous office actions of record, it is a matter of law that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed

invention. Therefore, any reliance on the data additionally supplied by the Declaration of Hitoshi is considered to be insufficient to overcome the instant rejection.

Thus, because the instant specification does not disclose a specific, substantial and credible “real world” use for the claimed novel polynucleotide sequences encoding 2.2412 protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. Claims 1, 5-7, 19-22, 24-29 and 32 are rejected under 35 U.S.C. 112, first paragraph for reasons of record in appropriate sections of previous communications of record.
8. Claims 1, 5-7, 20, 22, 24-26 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in Paper No. 12, No. 22 and No. 31.

Applicant argues that the instant specification discloses the amino acid sequence of 2.2412 protein and also identifies “ankyrin-type repeats and additional repeat sequences within the protein” (bottom at page 4 of the Response). Therefore, “[g]iven this information, the ordinarily skilled artisan can readily determine where 2.2412 protein can tolerate amino acid changes, including conservative amino acid changes” (top at page 5). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

2.2412 polynucleotides of the instant invention are asserted to be used as tumor markers.

The instant specification provided a written description of the full sequence of 2.2412 polynucleotide of SEQ ID NO: 1 and failed to describe any other molecular embodiment that lacks the polynucleotide sequence of SEQ ID NO: 1 (such as having 95% identity to SEQ ID NO: 1), which can be used as a tumor marker. With regards to Applicant's argument about "ankyrin-type repeats and additional repeat sequences within the protein", there appears to be no identified clear correlation between structure of the repeats and the ability to bind Grb7 and to function as tumor marker.

Therefore, for reasons fully explained earlier and reasons of record in the instant office action, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER